

# NIH POLICY MANUAL

## 3044-2, Protection of NIH Personnel Who Work with Nonhuman Primates

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1. **Explanation of Material Transmitted:** This policy establishes requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care with the intent to minimize the overall number of accidents and injuries sustained by NIH employees, contractors, and other personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates.

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PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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## PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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### A. PURPOSE:

This policy establishes requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care with the intent to minimize the overall number of accidents and injuries sustained by NIH employees, contractors, and other personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates.

### B. REFERENCES:

1. Guide for Care and Use of Laboratory Animals, NRC 1996
2. Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997
3. NIH Policy Manual 3015, "Admittance of Children to Hazardous Areas", 2/14/96
4. NIH Policy Manual 1340, "NIH Occupational Safety and Health Management", 11/29/96
5. NIH Occupational Medical Service: Animal Exposure Surveillance Program
6. Cohen, J.I., et al, "Prevention of and Therapy for B Virus Exposure", Clinical Infectious Diseases, 2002; 35:1191-203.

### C. DEFINITIONS:

1. **Animal Exposure Surveillance Program (AESP)** - That portion of the NIH occupational health program, managed by the Occupational Medical Services, Division of Occupational Health and Safety, specifically designed for all NIH personnel who work in animal facilities and/or areas where research animals are housed or used and who have significant contact, (as determined by the Principal Investigator or Immediate Supervisor), with research animals or their fresh tissues or body fluids. Institute and Center programs outside the metropolitan Washington DC area, e.g. NCCR's Alamogordo Primate Facility, NIA, NIDA, NIEHS and NIAID-RML, shall implement equivalent programs, as appropriate.
2. **Animal Research Advisory Committee (ARAC)** – The ARAC is a component of the NIH Intramural Animal Research Program that includes the Chairs of each IC Animal Care and Use Committee, and which serves as an advisory body to the Institutional Official.
3. **ARAC Guidelines** - Guidelines developed and approved by the ARAC to assist the NIH Intramural Animal Research Program in providing consistent care and use across IC's.
4. **Animal Study Proposal (ASP)** – written plan for research involving animal models that must be reviewed and approved by the IC ACUC before animal activities can be conducted.

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5. **Awake procedure** – activities and/or manipulations that would place an individual at reasonable risk of contact with an awake monkey or its feces or body fluids. Examples of awake procedures would include placing food in a cage or feedbox, using a squeezeback mechanism, jumping a monkey to another cage or transport device, pole and collar work, placing in a chair or other restraint device or behavior recording within a 2 ft radius. Awake procedures would not necessarily include activities such as entering a monkey holding room or lab space or viewing/observing animals for health assessment or behavior recording when standing outside a 2 foot radius.

6. **Awake Procedure Trainer** – individual that is responsible for initially documenting trainee competency and is responsible for providing additional awake procedures training, if needed. This would be the Principal Investigator/Immediate Supervisor or their designee.

7. **Contract Personnel** - Individuals employed by a contract company to provide services at NIH.

8. **Division of Occupational Health and Safety (DOHS)** – Serves as the NIH operational component in developing and implementing NIH-wide safety and health programs through surveillance, consultation, training and education.

9. **Facility Management** – An individual or individuals at each nonhuman primate (NHP) facility with direct responsibility for the NHPs and/or facilities that may contain an NHP.

10. **Institute/Center (IC)** – For the purposes of this policy manual, programs within the NIH Intramural Research Program that participate in animal-based research.

11. **IC-Animal Care and Use Committee (IC-ACUC)** - A committee appointed via delegated authority from the Institutional Official by the Director or Scientific Director of the IC. The committee oversees the IC's animal research program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in Animal Study Proposals.

12. **Immediate Supervisor (IS)** – individual with direct responsibility for personnel listed as trainees under this chapter. The IS can include facility managers, facility veterinarians, PI staff, contract managers, etc.

13. **Institution** – The NIH intramural program including facilities in Bethesda, other NIH facilities separate from the main campus, or contracted or subcontracted activities performed in accordance with NIH Policy Manual 3040-3 or other applicable acquisition regulations, in support of the intramural program.

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14. **Institutional Official (IO)** – The NIH Deputy Director for Intramural Research (DDIR). The Director, NIH, as the Chief Executive Officer of the institution, has delegated to the DDIR the authority and responsibility for compliance of the NIH Intramural Research Program with PHS Policy, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Regulations. This authority is referenced under NIH Manual 1130, Program: General #31, “NIH Intramural Animal Care and Use Program”.

15. **Macaque** – A genera of old world monkeys that has multiple species commonly used in biomedical research, such as rhesus, cynomolgus, and pigtail.

16. **Nonhuman Primate (NHP)** – any monkey species held or used for research at NIH.

17. **NHP Course Trainer** – individuals at the IC and/or facility level that conduct one or both portions of the “Working Safely with Nonhuman Primates” training course. This can include animal care staff members or research staff members. Typically these individuals are involved with the daily care or oversight of care for the IC’s NHP population.

18. **NHP Facility** – Any buildings, rooms, or areas, including satellite facilities and lab spaces, where NHPs may be housed or held for research manipulations to include surgical manipulations and imaging.

19. **Occupational Medical Service (OMS)** – A component of DOHS that develops and implements the Animal Exposure Surveillance Program.

20. **Other Personnel** – Individuals that are not NIH federal or contract employees. This can include transient visitors (ACUC non-affiliated members, maintenance staff, etc.), special volunteers, guest workers, and postdoctoral fellows.

21. **Personal Protective Equipment (PPE)** – Items of clothing (i.e. lab coats, shoe covers, face masks, gloves, etc.) or equipment (i.e. face shields, eye goggles, etc.) designed to prevent or limit exposure to potentially harmful agents.

22. **Principal Investigator (PI)** – A scientist designated by the Laboratory/Branch Chief or the IC Director or Scientific Director who is responsible for conducting or managing an animal study in compliance with this policy, PHS Policy, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Regulations, and who certifies acceptance of this responsibility by signing the Animal Study Proposal.

23. **Standard Operating Procedure (SOP)** – Written procedures that describe, in detail, how to perform a particular task or overall duty/responsibility.

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24. **Trainee** – Those individuals who do not have documented training and experience in handling and working with nonhuman primates.

#### D. RESPONSIBILITIES

1. DOHS is responsible for:

a. Providing general guidance on the selection and use of personal protective equipment for animal facilities and other areas that support animal research. Specific PPE guidance shall also be provided for work involving infectious diseases, hazardous chemicals, etc., that may require additional PPE. If respirators are occupationally required, DOHS will select and approve them.

b. Periodically reviewing training documentation as part of their safety inspections.

c. Reviewing training documentation as part of an incident investigation involving a NHP-related injury or illness.

d. Regularly reviewing injury and illness occupational reports and making accident information available to the Training Coordinator, OACU.

e. Providing appropriate medical support services for animal research (e.g. preplacement medical evaluations, care for work related injuries and illnesses, and an AESP) including Worker's Compensation support.

2. IC ACUC is responsible for:

a. Ensuring that all individuals working with NHPs receive initial safety awareness training by completing the "Working Safely with Nonhuman Primates" course as outlined in section E3. below.

b. Ensuring that those individuals working with awake NHPs receive competency assessment, and additional training (if needed). For the IC's investigative staff, the performance of awake procedures will be delineated in the PI's Animal Study Proposal(s). Competency for performing these procedures will be documented for the animal users on their ASP Training and Experience forms and if additional training is needed, this will be documented in the PIs training records. For the animal program staff, their awake procedures will be delineated in facility SOPs, and their training and experience for performing the procedures will be documented in the facility's training records.

3. Training Coordinator, OACU is responsible for:

a. Developing and managing the program for training intramural personnel to work safely and humanely with NHPs that adheres to the standards set by DOHS.

b. Ensuring that training will address DOHS-identified accident report trends of potential problem areas.

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4. Principal Investigator (PI) or Immediate Supervisor (IS) is responsible for:
  - a. Ensuring compliance from all personnel that work with NHPs with all provisions of this PM and any other special requirements or procedures specific to the facility within which they are working. To ensure compliance with the requirements of the "Working Safely with Nonhuman Primates" course, the PI/IS will complete both components of this course, even if they will not be working directly with the NHP's. In addition the PI/IS will take corrective action for failure to comply with the provisions of this policy.
  - b. Being prepared to provide copies of all training documentation to DOHS during routine safety surveys for periodic review, and/or having copies available for DOHS during incident investigations involving NHP-related injuries or illnesses.
  - c. Being prepared to provide copies of all training documentation to their IC ACUC if requested.
  - d. Ensuring documentation of the trainee's competency, and the provision of additional training, if needed, for the performance of any procedures the trainee will be performing with an awake NHP prior to allowing the trainee to perform these procedures independently.
  - e. Ensuring the provision and documentation of refresher training (both initial safety awareness training and awake procedures training, if applicable) for any returning trainee (e.g., summer students) who has not performed procedures with a NHP within a period of 6 months.
5. Trainee is responsible for adhering to all provisions of this Policy Manual, completing the initial safety awareness training, and any additional training that their PI/IS has established for them prior to attempting unsupervised, procedures on a NHP.
6. Facility Management is responsible for:
  - a. Providing and maintaining NHP bite/scratch/splash kits.
  - b. Obtaining clinical samples from NHPs that are involved in personnel-related accidents or illnesses.
7. NHP Course Trainers are responsible for:
  - a. Conducting one or both components of the safety awareness training course: "Working Safely with NHPs".
  - b. Forwarding NHP Course training rosters to the Training Coordinator, OACU, for the second component of the training. Training rosters for the first component, if conducted separately, should be kept at the IC level.

**E. POLICY AND PROCEDURES**

1. Personnel Restrictions
  - a. All personnel who have not been appropriately trained, and will be entering facilities containing NHPs must be accompanied by a responsible facility staff member

PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES who is knowledgeable in the behavior and handling of nonhuman NHPs.

b. Minors (individuals under 18 years of age) may not work with or be present for procedures or research activities involving awake NHPs. Minors under 16 years of age may not enter a room or area containing a NHP.

2. Compliance. All NIH employees, contract personnel and other personnel working directly with NHPs shall comply with procedures set forth in this Policy Manual. Continued failure to comply with requirements set forth in this policy shall be reported to the Scientific Director and/or Institute Director and may result in suspension of the privilege to use NHPs in research protocols or other disciplinary action. The Institutional Official shall be informed of such infractions and may impose additional disciplinary actions.

3. Training.

a. All personnel working directly with NHPs or regularly entering a facility containing NHPs shall complete the "Working Safely with NHPs" safety awareness training course prior to unsupervised entry. Those individuals having interaction with awake NHPs may also need additional training in approaching and handling NHPs. Certification is ensured by the Principal Investigator or Immediate Supervisor that a basic level of competency in performing awake procedures has been achieved. See PI/IS responsibilities paragraph D.4.

b. The safety awareness training course: "Working Safely with NHPs" (NHP Course) consists of two components:

- 1) "Working Safely with NHPs" video/CD, quiz and review of pertinent Safety Policy Manuals;
- 2) review of facility PPE requirements and location of bite/scratch/splash kits and eyewash stations.

The first component of the training is the responsibility of each IC that owns NHPs and may be offered separately at the Institute level or may be delegated to other responsible individuals. The second component must be conducted at the NHP facility level. Personnel entering multiple facilities where they work directly with NHPs or entering NHP facilities without supervision, must complete the second component of the training for each facility. Training documentation for the NHP Course will be provided to the Training Coordinator, OACU, only after both components are completed and should be forwarded by the facility-based NHP Course Trainers.

4. Personal Protective Equipment. All individuals entering a NHP room must wear appropriate personal protective clothing and equipment which meets or exceeds the guidance established by the NIH Animal Research Advisory Committee (ARAC): Guidelines for Personnel Protection and Minimum Requirements for Protective Clothing in Animal Facilities (Appendix). Individuals participating in animal study proposals (ASP) that involve additional safety hazards such as infectious diseases or hazardous

PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES chemicals must consult with the DOHS for proper guidance on PPE use for each ASP.

5. Medical Surveillance.

a. All persons having direct contact with NHPs and their tissues or body fluids must participate in the NIH Animal Exposure Surveillance Program (AESP) provided by the Occupational Medical Service (OMS).

b. All contract personnel having direct contact with NHPs and their tissues or body fluids must participate in an AESP that is equivalent to that of the NIH and which is provided by their employer.

c. Personnel who do not directly handle the NHPs and/or infrequently enter a facility containing NHPs are not required to participate in the AESP but are to wear single-use dust/mist masks in addition to other required protective clothing. In addition, these individuals may be asked to adhere to the facility's SOP for health screening (e.g. TB testing and Measles titer) prior to entering NHP areas.

6. Injury/Illness Reporting. All personnel involved in accidents and injuries involving NHPs, NHP wastes, or potentially contaminated equipment must report to their PI/IS *after* initial wound or mucous membrane care is completed and appropriate medical treatment is sought. They must then report to OMS (or appropriate designated hospital) as soon as possible for additional treatment and/or follow-up care. In addition, they should promptly notify the facility management responsible for the NHP or its equipment.

7. Wound Care. The management staff for each NHP facility is responsible for maintaining an adequately stocked bite/scratch/splash kit. The bite/scratch/splash kit must be located in an easily accessible area, and instructions for first aid (to include use of eyewash stations, if saline is not provided) and reporting to OMS (or designated hospital) must be prominently displayed. The first aid instructions for bite/scratch or lacerations should discuss initiation of wound scrubbing within 5 minutes of the incident, with an antibacterial soap, and that scrubbing should continue for at least 15 minutes. And for eye, mouth or nose splashes, that flushing of the area with saline solution or at an eye wash station (ocular exposures) should also be initiated within 5 minutes and continue for at least 15 minutes. The facility NHP Course Trainers are responsible for showing all research and animal care staff the location of the bite/scratch/splash kits and eyewash stations as part of the second component of the "Working Safely with NHPs" training.

8. Fresh Tissue/Body Fluid Users

a. Macaque tissue/body fluids – personnel that receive macaque fresh tissues and/or body fluids, and are not listed on an ASP, must enroll in the AESP program through OMS (or equivalent programs for contract personnel), must complete a Human Pathogen Registration Document for DOHS and must attend the Blood Borne Pathogen course offered by DOHS prior to receiving the tissues or fluids. These measures are in

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b. All other NHP tissue/body fluid – personnel that receive fresh tissues and/or body fluids from NHP species other than macaques, and are not listed on an ASP, are only required to enroll in the AESP program through OMS (or equivalent program).

**F. RECORDS RETENTION and DISPOSAL:**

1. All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, “Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule”, Items: 1100-H-2, committee records; 3000-C, DVR, ORS records; and 3000-G-2-a, biomedical research protocol records related to animal use.

2. NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information. All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees’ supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual’s computer. The back-up files are subject to the same requests as the original messages.

**G. MANAGEMENT CONTROLS:** The purpose of this manual is to establish requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care with the intent to minimize the overall number of accidents and injuries sustained by NIH employees, special volunteers, and visitors who work with nonhuman primates or enter nonhuman primate rooms.

**1. Office Responsible for Reviewing Management Controls Relative to this Chapter:** Office of Animal Care and Use and the Office of Intramural Research.

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**2. Frequency of Review (in years):** Ongoing with formal reports presented to the Animal Research Advisory Committee (ARAC) semiannually, annually and triennially as described below.

**3. Method of Review:**

The procedures implemented by this chapter receive an ongoing review by the Office of Animal Care and Use via their interface with all Intramural ACUC's on a continuous basis. Any significant changes in training policies or animal procedures are noted and acted upon as needed rather than at a specified time.

Semi-annually the IC ACUC's perform a complete review of their animal care programs, a component of which is a review of the adequacy of IC training and experience. These semi-annual reports are filed with OACU. The OACU staff members review these reports, prior to their submission for review by the DDIR, and the OACU Director then provides a consolidated report to the ARAC regarding trends, concerns, etc. that affect the Intramural Animal Care Program (ACP).

Annually the Division of Occupational Health and Safety compiles a report of bite and scratch injuries related to work with nonhuman primates and presents this to the NIH Occupational Safety and Health Committee and the ARAC. This report provides a basis for discussion of trends seen within this work arena and provides an avenue for both the NIH as well as the Intramural ACUC's to develop new guidance if concerns exist.

Triennially, the Intramural ACU program is visited by their accrediting organization, the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Training and experience with NHPs is a part of AAALAC's extensive review of the NIH. AAALAC provides a report of their findings to NIH which in turn are presented to the ARAC for deliberation and resolution.

The Intramural Program must make annual reports to both the United States Department of Agriculture and the NIH Office of Laboratory Animal Welfare (OLAW.) These agencies have regulatory authorities over the NIH IRP ACU program. Per the PHS Policy, instances of significant noncompliance are required to be reported to OLAW. In addition, the Association for Assessment and Accreditation of Laboratory Animal Care International performs triennial peer review site visits to all NIH components who use animals in their IRP programs.

In addition, the IC Directors or Scientific Directors participate in the Annual Intramural Self Assessment of Management Controls, through completion of a set of comprehensive checklists of questions, several of which address concerns covered by this chapter. This process is managed by the Office of Intramural Research.

**4. Review Reports** are sent to: the Deputy Director for Intramural Research and the Deputy Director for Management.

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**Appendix**

**Guidelines for Personnel Protection and Minimum Requirements  
for Protective Clothing in Animal Facilities**

*(excerpt: only includes nonhuman primate information.*

The complete guideline is available at: <http://oacu.od.nih.gov/ARAC/clothes.pdf>)

**Purpose:** The primary intent of this guideline is to provide a basis for discussion of risk when working with various animal species and specific protective measures to reduce the risk, with an emphasis on personnel protective equipment. Two principles serve as the basis for selecting appropriate protective measures: 1) reducing or avoiding animal related accidents by understanding the potential for physical risks unique to each species, i.e. biting, scratching, kicking, etc.; and 2) decreasing or eliminating exposure to zoonotic diseases by understanding common diseases that may be encountered with each species. For a protective program to be effective, personnel working with animals should be convinced that the recommendations in place will significantly increase their safety. As such the most important preventive strategy is providing education and training in proper animal interactions and handling, and proper use of protective clothing and equipment. Personnel who are knowledgeable about the risks they face with a given species of animal and the protection offered by each device, article of clothing, and procedure should in turn be motivated to comply with the protection program. See table below for recommended levels of PPE for use in NHP facilities.

In addition to the protection provided by Personal Protective Equipment (PPE), hand washing is an important adjunct to the use of exam gloves or in place of exam gloves for prevention of the spread of infectious organisms or other contaminants to both personnel and animals. While the use of exam gloves will greatly decrease the spread of contaminants from a person's hands, they will not completely eliminate this transfer due to micro-breaks in the glove materials, regardless of type (latex, vinyl or nitrile). For effective hand washing, antimicrobial soaps or alcohol-based hand rubs are recommended for use.

**Limits:** This guideline should be used as a basis for developing internal Standard Operating Procedures for each site. This guideline is not meant to cover all the specific concerns that might be encountered in animal facilities, areas or labs, or to limit the requirements of these sites. Nor does this guideline intend to establish requirements for experiments that have special safety requirements such as the use of infectious disease organisms, hazardous chemicals or radiation sources, or for individuals with special health needs, such as pregnancy or immune deficiency. Personnel with questions regarding any research related safety concern or may have a specific health concern, should contact the Division of Occupational Health and Safety (DOHS), the Division of Radiation Safety (DRS), or the Occupational Medical Services (OMS).

Approved by ARAC – 11/9/92  
Reapproved - 5/8/96, 2/10/99  
Revised - 3/27/02, 03/09/05

**PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES**  
**Protective Clothing Requirements for Personnel in Nonhuman Primate Facilities**

ACTIVITY	REQUIREMENTS
View animals in the primate room. No contact with the animals or the cages	Mucous membrane protection as appropriate* and street clothes covering, hand washing should be performed upon leaving the area and after any of the following activities.
Contact with a restraint device holding an awake animal	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Transfer alert monkey using a stand-off method such as pole/collar technique or transfer cage	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Handling (e.g. hand catching or restraining) of an alert monkey.	Mucous membrane protection appropriate for high risk situations, street clothes covering and arm length bite protection gloves.
Physical contact with an anesthetized monkey.	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Cleaning cages.	Mucous membrane protection appropriate for high risk situations, dedicated clothing, dedicated shoes, and light gloves; dust-mist masks, if approved by DOHS.
Physical contact with restrained alert monkey	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Physical contact with infant monkeys	Mucous membrane protection as appropriate*, street clothes covering and light gloves. As infants mature, heavier gloves may be required.
Perform portions of experiments in a laboratory that do not involve physical contact with monkey or body fluids.	Protection appropriate for non-animal aspects of research.
Handling awake New World Species	Mucous membrane protection as appropriate*, street clothes covering, protective gloves appropriate for the species and size of animal being handled. Larger species such as Cebus should be handled with the arm length bite protection gloves, while very small species such as marmosets may be handled with lighter weight protection.

\* Mucous membrane protection should be appropriate to the potential for splash hazard. The level of mucous membrane protection should be detailed in facility standard operating procedures (SOP's). SOP's are subject to review and approval by the IC ACUC with the concurrence of the Division of Occupational Health and Safety with consult by the IBC as necessary. The degree of risk involved in entering an animal holding room or working with awake animals varies with the design of the facility, the species involved and the nature of the task being performed. **Examples** of high risk situations include any procedures which may aerosolize NHP wastes or body fluids, e.g. hosing down animal rooms, dental work or tracheal intubation, especially of macaques. Lower risks are associated with fully restrained animals, anesthetized animals (However, Ketamine increases salivation which is a major source of potential B virus contamination from macaques.), and increased distance from animals. In very low risk situations, e.g. entering hallways through which animals in restraint devices may briefly pass, mucous membrane protection may not be required. The future definition and availability of SPF animals may alter these requirements.